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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,519	01/03/2002	Catherine A. McCall	SC-1-C2	6037
7590	10/19/2004		EXAMINER	
Heska Corporation 1613 Prospect Parkway Fort Collins, CO 80525			YANG, NELSON C	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 10/19/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/038,519

### Applicant(s)

MCCALL ET AL.

### Examiner

Nelson Yang

### Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,9-11,20-22 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,9-11,20-22 and 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/9/02.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

- I. Applicant's amendment of claims 1 and 10 is acknowledged.
  - 1. Applicant's cancellation of claims 5-8, 12-19, 23-24 is acknowledged.
  - 2. Applicant's addition of claims 25-29 is acknowledged.
  - 3. Currently claims 1-4, 9-11, 20-22, 25-29 are pending.

### ***Rejections Withdrawn***

- II. Applicant's arguments, see page 6, filed August 28, 2004, with respect to the rejection of claim 4 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claim 4 under 35 U.S.C. 112, second paragraph has been withdrawn.
- 4. Applicant's arguments, see page 6, filed August 28, 2004, with respect to the objection of claims 5-8 have been fully considered and are persuasive. The objection of claims 5-8 has been withdrawn.

### ***Information Disclosure Statement***

- III. The abstracts of the unconsidered foreign references cited in the IDS submitted December 09, 2002, have been considered.

### ***Claim Rejections - 35 USC § 102***

- IV. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Marinkovich et al [US 4,558,013].

With respect to claims 1, 20, Marinkovich et al teach an apparatus comprising coated test regions on a carrier. The coated test regions can be spots on a carrier (figs. 1-3) and take the form of separate cotton threads coated with a different binding conjugate for the immunoglobulin whose presence is to be detected and measured (column 2, lines 35-45). The carrier produces a strip of photographic film having a linear array of transverse spots or stripes, each having an optical density indicating the magnitude of the reaction for a particular test thread (column 3, line 65 – column 4, line 5). Marinkovich et al further teach a control spot comprising a positive reference thread, coated directly with IgE itself (column 6, lines 48-51).

6. With respect to claims 2-3, Marinkovich teach that all but a few of the threads are designated to be test threads, i.e., are individually coated with prescribed concentrations of various allergens (column 4, lines 45-48).

7. Claims 1-4, 9-11, 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Hubscher et al [US 6,528,325].

With respect to claims 1, 20, Hubscher et al teach a lateral flow immunoassay device (column 3, lines 35-40), capable of detection of the IgE class of antibody to many allergens coated sequentially on a bibulous strip. As the reaction front moves transversely down the strip toward an absorbent pad, sufficient IgE specific antibody molecules are available to react with

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the various allergens (column 3, lines 50-56). Hubscher et al further teach a positive control comprising a protein or substance that can be an antibody reactive with the proteins coated on the gold or microparticles surface (column 8, line 60 – column 9, line 5). Since the proteins coated on the gold surface are anti-IgE antibodies (column 8, lines 30-35), the antibodies located on the positive control would be IgE antibodies.

8. With respect to claims 2-3, the device can be used to test for one or more different allergens, preferably by one strip, two strips, or multiple strips next to each other, where each strip can contain one or more allergen lines (column 8, lines 35-40).
9. With respect to claim 4, the sample receiving area is separate from the area of the test strip with allergens deposited (fig. 2).
10. With respect to claim 9, Hubscher et al teach that the reaction front moves transversely down the strip toward an absorbent pad (column 3, lines 50-56).
11. With respect to claim 10, Hubscher et al teach that the lateral flow device can be used for the visual detection of allergen specific IgE antibodies in human or animal serum (column 8, lines 29-31).
12. With respect to claim 11, Hubscher et al teach that the mixture of allergens can comprise pollens, cat epithelium, dog dander, legumes, and other allergens (column 8, lines 29-59).
13. With respect to claims 21-22, Hubscher et al teaches a lateral flow immunoassay device (column 3, lines 35-40).

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V. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubscher et al [US 6,528,325].

With respect to claims 25-27, Hubscher et al teach that the lateral flow device can be used for the visual detection of allergen specific IgE antibodies in human or animal serum (column 8, lines 29-31). Although Hubscher et al do not specifically teach that the animal serum can be canine, feline, or equine, it would have been obvious to one of ordinary skill in the art to use canine, feline, or equine serum containing allergen specific IgE antibodies as examples of animal serum through normal experimental techniques known in the art.

15. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marinkovich et al [US 4,558,013] in view of Mita et al [Mita et al, Affinity of IgE antibody to antigen influences allergen-induced histamine release, 2000, Clin Exp Aller, 30, p.1582-1589].

Marinkovich et al teach a device comprising a positive control, but fail to specifically teach the positive controls comprising anti-IgE immunoglobulin or IgE receptors.

Mita et al, however, do teach that positive controls comprising varying concentrations of anti-IgE and Der p 2 (p.1583, col.2) to determine concentrations of IgE in the serum. Mita et al further teach that to evaluate the efficacy of IgE antibodies in vitro, it is assumed that the

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histamine release may be dependent on the affinity of the IgE antibody for the allergen (p.1583, col.1).

Therefore it would have been obvious to use anti-IgE antibodies in the device of Marinkovich et al as a positive control, in order to determine the affinity of IgE for the allergens, relative to anti-IgE antibodies.

16. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubscher et al [US 6,528,325] in view of Mita et al [Mita et al, Affinity of IgE antibody to antigen influences allergen-induced histamine release, 2000, Clin Exp Aller, 30, p.1582-1589].

Hubscher et al teach a device comprising a positive control, but fail to specifically teach the positive controls comprising anti-IgE immunoglobulin or IgE receptors.

Mita et al, however, do teach that positive controls comprising varying concentrations of anti-IgE and Der p 2(p.1583, col.2) to determine concentrations of IgE in the serum. Mita et al further teach that to evaluate the efficacy of IgE antibodies in vitro, it is assumed that the histamine release may be dependent on the affinity of the IgE antibody for the allergen (p.1583, col.1).

Therefore it would have been obvious to use anti-IgE antibodies in the device of Hubscher et al as a positive control, in order to determine the affinity of IgE for the allergens, relative to anti-IgE antibodies.

### ***Response to Arguments***

VI. Applicant's arguments with respect to claims 1-4, 9-11, 20-22 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***


VII. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang  
Patent Examiner  
Art Unit 1641

  
BAO-THUY L. NGUYEN  
PRIMARY EXAMINER  
10/15/04